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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/830,113	04/23/2004	Jong-youn Lee	249/463	9017

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EXAMINER

BAXTER, ZOE E

ART UNIT PAPER NUMBER

3735

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/830,113	<b>Applicant(s)</b> LEE ET AL.	
	<b>Examiner</b> Zoe E. Baxter	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed July 7, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.
2. The Information Disclosure Statements (IDS) submitted on November 01, 2004 and April 23, 2004 are acknowledged. Since the Information Disclosure Statements comply with 37 CFR 1.97 and 37 CFR 1.98 the references submitted there in have been considered.

### ***Claim Rejections - 35 USC § 101***

1. Claim 4 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim refers to applying light signals to the predetermined part of the subject's body; one cannot claim a positive relationship to the body. It is suggested that the claim recite that the light source is adapted to apply light to the body.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. The term "several" in claim 15 is a relative term, which renders the claim indefinite. The term "several" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is also unclear as to which value is being used as the reference a normal breathing state or the breathing cessation state. In order to overcome this rejection the applicant needs to clearly state how the predetermined reference value is to be calculated. So that one skilled in the art is able to reproduce the method of comparison.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamanishi et al. (U.S. Patent No. 5385144). Yamanishi et al. discloses a light source unit generating two wavelengths of light (column 2 lines 42-45), a photodetecting unit for detecting first and second light signals output by the light source, applied to a part of the subjects body and converts the light signals to electric signals, (column 2 lines 48-51), a diagnosis unit for calculating the ratio between first and second electric signals and comparing with a reference value to diagnose sleep apnea (column 3 lines 38-43),

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Yamanishi et al. measure the oxygen saturation, it is well known to one skilled in the art that an oxygen saturation calculation from two wavelengths of light one being red and one being near infrared wavelengths as simply a ratio of the two wavelengths Vurek (U.S. Patent No. 3799672) further verifies this (column 1 lines 6-12) Yamanishi measures the oxygen saturation, but does not disclose using the recited ratio. Vurek teaches what is well known, that oxygen saturation is determined as the ratio. Therefore, it would have been obvious to modify Yamanishi to calculate saturation as taught by Vurek, as it is merely use of a well known formula in the art. Finally Yamanishi et al. uses a slave microcomputer (5) to control the two light emitting diodes (column 2 line 46-49) and a master microcomputer (6) to hold the predetermined reference value (column 3 lines 36-42). Combined the two computers can be considered a comparable controller as claimed by the applicant.

6. Claim 2 is anticipated by Yamanishi et al. Yamanishi et al disclose an apparatus wherein the light source unit is a light emitting diode array that generates light in a red wavelength and an infrared wavelength (column 42-45).

7. Claim 3 is anticipated by Yamanishi et al. The inventor is claiming an apparatus wherein the light source unit comprises a light source for generating the first and second light signals and a driver for driving the light source. The slave microcomputer (5) in addition to the Light emitting diode array are taking on the function of a light source unit, in that the microcomputer drives the output of the light emitting diode array (column 2 lines 42-48).

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8. Claim 4 is anticipated by Yamanishi et al. Yamanishi et al. disclose generating a light signal applying it to a subject's fingertip etc. and measuring the amount of light that is transmitted through or is reflected off a patient's fingertip and converting this to an electrical signal (column 2 lines 49-51). The electrical signal, which is then calculated as an arterial blood oxygen saturation value (column 3 lines 38-39) since they are measuring an arterial blood oxygen saturation the device would have to be used where there is an arterial pulsating component.

9. Claim 5 is anticipated by Yamanishi et al. Yamanishi et al. describe two methods of driving the red light emitting diode and infrared light emitting diode one using a time sharing-basis and the other being driven by a variable alternating frequency or phase (column 3 lines 7-10).

10. Claim 11 is anticipated by Yamanishi et al. In describing an apparatus Yamanishi et al. are also implying that there is a method that the apparatus uses. They disclose sequentially generating two light signals being of different wavelengths (column 2 lines 42-45), applying the light signals to a part of the subject's body, detecting the light signals and converting them into two electrical signals (column 2 lines 48-51), sampling the converted electric signals respectively delaying the first and second electric signals to remove a time difference between the two electric signals and calculating a ratio of the first and second electric signals and comparing the ratio with a predetermined reference value to determine the presence of sleep apnea (column 3 lines 36-66).

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11. Claim 12 is anticipated by Yamanishi et al. Yamanishi et al. discloses that the first wavelength is in a red wavelength range and the second is in an infrared wavelength range (column 2 lines 42-45).

12. Claim 13 is anticipated by Yamanishi et al. Yamanishi et al. discloses a method wherein applying the first and second light signals comprises applying the first and second light signals to the predetermined part of the subject's body where an arterial pulsating component is measured. It is stated that the light is passing through the subjects finger etc (column 2 lines 45-46) and it measures an arterial blood oxygen saturation value (column 3 lines 38-40) it is inherent that since the device is measuring an arterial blood oxygenation saturation value the sensor must be placed where an arterial pulsating component is being measured.

13. Claim 14 is anticipated by Yamanishi et al. Yamanishi et al. discloses a method wherein applying the first and second light signals comprises applying the first and second light signals to the predetermined part of the subject's body where an arterial pulsating component is measured. It is stated that the light is passing through the subjects finger etc (column 2 lines 45-46) and it measures an arterial blood oxygen saturation value (column 3 lines 38-40) it is inherent that since the device is measuring an arterial blood oxygenation saturation value the sensor must be placed where an arterial pulsating component is being measured.

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanishi et al. in view of Zelin (U.S. Patent No 4819752) and further in view of Sackner et al. (U.S. Patent No. 5588425). Yamanishi et al. discloses a photodetector for detecting the first and second light signals generated by the light source and applied to the predetermined part of the subject's body. Zelin teaches a method of using a current to voltage converter for converting the first and second current electric signals into first and second voltage electric signals which would be used in an analog configuration as opposed to using a digital output. Sackner et al. further states that pulse oximeters have analog or digital outputs for values of arterial oxygen saturation as well as for pulse waveforms teaching that the applicant can use either a digital or analog output and it would simply be design choice to use analog data as opposed to using digital data. Therefore it would have been obvious to modify Yamanishi et al. to include a current to voltage converter, as it is merely the substitution of one known processing technique for another.

15. Claim 7 is rejected as being unpatentable over Yamanishi and Zelin as applied to claim 6 above. Zelin further teaches a method of using a demultiplexer producing two separate signals from the photodetecting unit (column 6 lines 56-58), a sample-and-hold



circuit which holds the sample to be compared with one that is later digitized by holding the output Zelin is essentially delaying the sampling (column 10 lines 1-3) and a divider for calculating a ratio of the first and second signals output from the delay unit is a microcomputer that determines the oxygen saturation which is defined as a ratio between the red and infrared wavelengths. The comparator portion is described in Yaminishi et al. using a microcomputer as the comparator for comparing an arterial blood oxygen saturation value to a corresponding standard value. As stated above Sackner et al. teach that pulse oximeters can have analog or digital outputs for the given values that it would be obvious that choosing one style over another is merely a design choice by the inventor.

16. Claim 8 is rejected as being unpatentable over Yamanishi and Zelin as applied to claim 7 above. Zelin discloses a method of using the sample-and-hold circuitry (column 9 lines 67-68) and an amplifier to amplify the signal (column 9 lines 16-22). Since the inventor chose to use an analog type system it would be obvious to combine the works of Yamanishi and Zelin since Zelin teaches a method of using analog signals as opposed to digitizing the signals from the output of the photodetector.

17. Claim 9 is rejected as being unpatentable over Yamanishi and Zelin. Zelin teaches a method of using a demultiplexer producing two separate signals from the photodetecting unit (column 6 lines 56-58), a sample-and-hold circuit which holds the sample to be compared with one that is later digitized by holding the output Zelin is essentially delaying the sampling (column 10 lines 1-3) and a divider for calculating a ratio of the first and second signals output from the delay unit is a microcomputer that

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determines the oxygen saturation which is defined as a ratio between the red and infrared wavelengths. The comparator portion is described in Yaminishi et al. using a microcomputer as the comparator for comparing an arterial blood oxygen saturation value to a corresponding standard value. As stated above Sackner et al. teach that pulse oximeters can have analog or digital outputs for the given values that it would be obvious that choosing one style over another is merely a design choice by the inventor.

18. Claim 10 is rejected as being unpatentable over Yamanishi and Zelin as applied to claim 9 above. Zelin discloses a method of using the sample-and-hold circuitry (column 9 lines 67-68) and an amplifier to amplify the signal (column 9 lines 16-22).

Since the inventor chose to use an analog type system it would be obvious to combine the works of Yamanishi and Zelin since Zelin teaches a method of using analog signals as opposed to digitizing the signals from the output of the photodetector.

19. Claim 15 is rejected as being unpatentable over Yamanishi et al., and further in view of Westbrook et al (U.S. Patent No. 6811538). Westbrook teaches averaging data across a wider time window as being a common technique embedded in a device to minimize false alarms due to measurement artifact. It would be obvious to one skilled in the art and use the knowledge provided by Westbrook et al. to take a sample from the subject to use as a reference point to ensure that normal or apnea values are accurate rather than giving a generic reference point.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zoe E. Baxter whose telephone number is 571-272-8964. The examiner can normally be reached on Monday-Friday 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zoe E. Baxter  
Examiner  
Art Unit 3736

ZEB

